

Amendments to the claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

1. (Original): An isolated compound, which is topotecan monohydrochloride pentahydrate, said compound having an x-ray diffraction pattern that is substantially the same as Figure 1.

2. (Original): An isolated compound, which is topotecan monohydrochloride pentahydrate, said compound having an inverse second derivative FT-IR spectrum for the spectral region of 1800 cm^{-1} - 1500 cm^{-1} that is substantially the same as Figure 3.

3. (Original): An isolated compound, which is topotecan monohydrochloride pentahydrate, wherein said compound provides an x-ray diffraction pattern having peaks at 4.5 ± 0.1 ($^{\circ} 2\theta$), 6.4 ± 0.1 ($^{\circ} 2\theta$), 7.1 ± 0.1 ($^{\circ} 2\theta$), 9.0 ± 0.1 ($^{\circ} 2\theta$), 10.1 ± 0.1 ($^{\circ} 2\theta$), 11.5 ± 0.1 ($^{\circ} 2\theta$), 12.6 ± 0.1 ($^{\circ} 2\theta$), 13.1 ± 0.1 ($^{\circ} 2\theta$), 14.1 ± 0.1 ($^{\circ} 2\theta$), 15.5 ± 0.1 ($^{\circ} 2\theta$), 17.9 ± 0.1 ($^{\circ} 2\theta$), 18.7 ± 0.1 ($^{\circ} 2\theta$), 20.0 ± 0.1 ($^{\circ} 2\theta$), 20.3 ± 0.1 ($^{\circ} 2\theta$), 21.1 ± 0.1 ($^{\circ} 2\theta$), 21.8 ± 0.1 ($^{\circ} 2\theta$), 23.0 ± 0.1 ($^{\circ} 2\theta$), 24.8 ± 0.1 ($^{\circ} 2\theta$), 25.6 ± 0.1 ($^{\circ} 2\theta$), 26.6 ± 0.1 ($^{\circ} 2\theta$), 27.2 ± 0.1 ($^{\circ} 2\theta$), and 28.9 ± 0.1 ($^{\circ} 2\theta$).

4. (Original): An isolated compound, which is topotecan monohydrochloride pentahydrate, wherein said compound provides an FT-IR spectrum having peaks at $1754 \pm 2\text{ cm}^{-1}$, $1745 \pm 2\text{ cm}^{-1}$, $1740 \pm 2\text{ cm}^{-1}$, $1658 \pm 2\text{ cm}^{-1}$, $1649 \pm 2\text{ cm}^{-1}$, $1596 \pm 2\text{ cm}^{-1}$, $1584 \pm 2\text{ cm}^{-1}$, and $1507 \pm 2\text{ cm}^{-1}$.

5. (Currently amended): The isolated compound according to claim 1 ~~any one of claims 1-4~~, wherein the topotecan monohydrochloride pentahydrate has a water content range between from about $\geq 10\%$ w/w% to about $\leq 17\%$ w/w%.

6. (Currently amended): The isolated compound according to claim 1 any one of claims 1-5, wherein the topotecan monohydrochloride pentahydrate has a water content in a range of about 10.5 wt% to about 16.5 wt%.

Claims 7-8 (Cancelled).

9. (Currently amended): A pharmaceutical composition comprising the compound according to claim 1 any one of claims 1-8 and a pharmaceutically acceptable carrier.

10. (Currently amended): A pharmaceutical composition according to claim 9, wherein the pharmaceutical composition is a hard gelatin capsule and the pharmaceutically acceptable carrier comprises glyceryl monostearate and hydrogenated vegetable oil.

11. (Currently amended): A process for preparing the isolated compound according to claim 1 any one of claims 1-8, wherein the process comprises steps of:

- [a] forming an aqueous organic solvent mixture containing topotecan monohydrochloride;
- [b] recrystallizing the topotecan monohydrochloride from and/or slurring the topotecan monohydrochloride with the aqueous organic solvent mixture to precipitate and/or form the topotecan monohydrochloride pentahydrate product; and
- [c] collecting, by filtration, said compound.

12. (Original): The process according to claim 11, wherein the aqueous organic solvent mixture comprises a mixture of acetone and a 0.05 N aqueous hydrochloric acid solution.

13. (Original): The process according to claim 12, wherein the ratio of the volume of acetone to aqueous hydrochloric acid is about 2:1.

14. (Original): The process according to claim 11, wherein the aqueous organic solvent mixture is heated to a temperature of about 58°C.

15. (Original): The process according to claim 14, wherein the heated aqueous organic solvent mixture is cooled at a rate in the range of about 0.1°C/min to about 1°C/min.

16. (Original): The process according to claim 15, wherein the cooling rate is about 0.25°C/min.

17. (Original): The process according to claim 11, wherein the aqueous organic solvent mixture comprises an organic solvent and an aqueous solvent in a ratio of about 2:1.

18. (Currently amended): A method of treating cancer which comprises administering to a subject in need thereof an effective amount of the compound according to claim 1 ~~any one of claims 1-8~~.

19. (Original): A method of treating cancer which comprises administering to a subject in need thereof an effective amount of the pharmaceutical composition according to claim 9.

20. (Currently amended): The method according to claim 18 ~~or claim 19~~, wherein said cancer is selected from the group of solid tumor types and non-solid tumor types.

21. (Currently amended): The method according to claim 18 ~~or claim 19~~, wherein said cancer is selected from the group of ovarian cancer, breast cancer, endometrial cancer, esophageal cancer, small and non-small cell lung cancer, cervical cancer, colorectal cancer, neuroblastomas and glioma.

22. (Currently amended): The method according to claim 18 ~~or claim 19~~, wherein said cancer is selected from the group of myelodysplastic syndrome, acute myelogenous leukemia and chronic myelomonocytic leukemia.

23. (Currently amended): A method for ameliorating one or more of the symptoms associated with cancer, which comprises administering to a subject in need thereof an effective amount of the compound according to claim 1 ~~any one of claims 1-8.~~

24. (Original): A method for ameliorating one or more of the symptoms associated with cancer, which comprises administering to a subject in need thereof an effective amount of the pharmaceutical composition according to claim 9.

25. (Currently amended): The method according to claim 23 or claim 24, wherein the one or more symptoms associated with cancer are selected from the group: pain, fatigue, insomnia, interference with daily activity, dyspnea, chest pain, hemoptysis and hoarseness.

Claims 26-28 (Cancelled).